PATENT

Appl. No. 09/834,410
Amdt. dated August 15, 2003
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended) A timed-release compression-coated solid composition for oral administration to a subject, said composition comprising:

a) a core tablet comprising a drug and a freely erodible filler, wherein said core tablet ~~is capable of~~ erodes approximately 40% to approximately 90% ~~erosion~~ in the digestive tract of said subject; ~~and~~

b) an outer layer, ~~said outlayer~~ wherein said outer layer is made from a hydrogel-forming polymer substance, and a hydrophilic base, wherein said ~~outer layer optionally contains a drug~~ hydrogel-forming polymer substance has a viscosity-average molecular weight of 2,000,000 or higher and/or a viscosity in an aqueous 1% solution (25° C) of 1,000 cp or higher, and said hydrophilic base having solubility such that the amount of water needed to dissolve 1g of said hydrophilic base is 5 mL or less; and

c) wherein the outer layer optionally contains another drug and the outer layer essentially does not contain the same drug as the core tablet drug.

2. (Cancel)

3. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein there is approximately 75 wt% or less of said drug, approximately 5 to approximately 80 wt% freely erodible filler, approximately 10 to approximately 95 wt% hydrogel-forming polymer substance, and approximately 5 to approximately 80 wt% hydrophilic base.

4. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler is 1 or 2 or more selected from the group consisting of malic acid, citric acid, tartaric acid, polyethylene glycol, sucrose, and lactulose.

5. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler is 1 or 2 or more selected from the group consisting of malic acid, citric acid and tartaric acid.

6. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler for a basic drug is 1 or 2 or more selected from the group consisting of malic acid, citric acid and tartaric acid.

7. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler for an acidic or neutral drug is 1 or 2 or more selected from the group consisting of polyethylene glycol, sucrose or lactulose.

8. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the hydrogel-forming polymer substance contains at least one type of polyethylene oxide.

9. (Cancel)

10. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the core tablet contains hydrogel-forming polymer substance.

11. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the hydrophilic base is 1 or 2 or more having solubility such that the amount of water needed to dissolve 1 g base is 5 mL or less.

12. (Original) The timed-release compression-coated solid composition for oral administration according to claim 11, wherein the hydrophilic base is 1 or 2 or more selected from the group consisting of polyethylene glycol, sucrose, and lactulose.

13. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the hydrogel-forming polymer substance is at least 1 type of polyethylene oxide and further contains red ferric oxide and/or yellow ferric oxide.

14. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug is brought to be effectively released or absorbed in the lower digestive tract.

15. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug is brought to be effective for chronopharmacotherapy.

16. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug is metabolized by cytochrome P-450.

17. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug has the effect of inhibiting metabolism by cytochrome P-450.

18. (Original) The timed-release compression-coated solid composition for oral administration according to claim 16, wherein the drug is metabolized by CYP3A4.

19. (Original) The timed-release compression-coated solid composition for oral administration according to claim 17, wherein the drug has the effect of inhibiting metabolism by CYP3A4.

20. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the drug is 4'-[(2-methyl-1,4,5,6-tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzanilide or its salt.

21. (Original) A method of timed release of a drug, whereby the composition in claim 1 is orally administered.

22. (Original) A method for alleviating undesirable drug interaction between a drug and other drugs used concomitantly that employ the same route for drug absorption, distribution, metabolism or excretion *in vivo* in humans, whereby the composition in claim 1 is orally administered.

23. (Original) A method of alleviating undesirable drug interaction with between a drug having the effect of inhibiting drug metabolism *in vivo* in humans and another drug according to claim 20 used concomitantly, whereby the composition in claim 1 is used.

24. (Original) In a hydrogel-forming compression-coated solid pharmaceutical preparation comprising: a core tablet containing drug and outer layer made from hydrogel-forming polymer substance and hydrophilic base, the improvement which comprises a timed-release compression-coated solid composition according to claim 1.

25. (Original) In a hydrogel-forming compression-coated solid pharmaceutical preparation comprising:

a core tablet containing drug and outer layer made from hydrogel-forming polymer substance and hydrophilic base, the improvement which comprises a timed-release compression-coated solid composition for oral administration, said composition comprising:

(1) a drug and freely erodible filler are mixed with the core tablet;

(2) the percentage erosion of the core tablet is approximately 40 to approximately 90%; and

(3) the outer layer essentially does not contain the same drug as the above-mentioned drug.

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26. (Original) The timed-release compression-coated solid composition for oral administration according to claim 25, wherein the drug is 4'-[(2-methyl-1,4,5,6-tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzanilide or its salt.